

**REMARKS**

Claims 68, 71, 73, 74, and 85-87 are all the claims pending in the application. Applicant thanks the Examiner for withdrawing rejections and objections from the previous Office Action. Please note that Applicant reserves the right to file subsequent applications encompassing any subject matter deleted or canceled from the claims; and that Applicant's present amendments should not be construed as abandonment of that subject matter nor an admission of the correctness of the Examiner's position.

Claim 87 has been amended to delete the comma between R<sub>3</sub> and R<sub>4</sub>, as was requested by the Examiner in an objection to that claim.

Rejections under 35 USC §112, first paragraph

1) Claims 68, 71, 85 and 87 have been rejected under as allegedly failing to comply with the written description requirement. In the last Response, Applicant provided that R<sub>3</sub> and R<sub>4</sub> could be C<sub>1</sub>-C<sub>5</sub> heteroalkyl with 0 to 6 sites of unsaturation and 0-5 heteroatoms. The Examiner has challenged the written descriptive support for this language and has stated that the Specification supports C<sub>1</sub>-C<sub>5</sub> heterogroups having one heteroatom.

Although Applicant traverses this rejection, in order to advance prosecution, he has amended these claims accordingly. Therefore, the rejection as to these claims should be rendered moot.

2) Claim 86 has been rejected as allegedly failing to comply with the written description requirement. According to the rejection, "the specification as originally filed fails to provide adequate written description of the chemical structure of the claimed" compounds, such

as DORIE carboxylate, DMRIE carboxylate, etc. Even though the claim provides for the full names of the compounds as well as the abbreviations, the rejection goes on to state: “the instant specification lacks any description of the exact chemical structure....Applicant cannot rely upon what is well-known and/or well-established in the prior art to provide adequate written description....” (See page 6 of the Office Action.)

Applicant respectfully traverses and asserts that one of skill in the chemical arts would understand the meaning of the terms in Claim 86 and would understand the associated structures. However, the following explanation is given to assist in comprehending the terminology.

The chemical name for DMRIE is provided in the Specification at page 3, lines 24-26 as: “N-(2-hydroxyethyl)-N,N-dimethyl-2,3-bis(tetradecyloxy)bromide, (±)-(CAS registry:146659)”. DMRIE has a C<sub>14</sub> structure whereas DORIE has a C<sub>18</sub> structure. (See page 3, line 23.) The structures for both DORIE and DMRIE also are given in the Nomenclature table on pages 28-29. As Applicant understands the Office Action, the Examiner is not questioning the written descriptive support for DORIE and DMRIE. In any event, Applicant has established that the chemical structures for DORIE and DMRIE are clearly and unequivocally described in the Specification. Therefore, the requirements of 35 USC §112, first paragraph are met for these compounds.

Starting with either DORIE or DMRIE, the compounds listed in Claim 86 were synthesized as stated in the Specification. Generally, the various syntheses are described under the heading “Summary of Synthetic Transformations” starting on page 52. Basically specific functionalities are appended via the quaternary nitrogen to create carboxy, carbamyl and urea

classes as shown in Schemes III, IV, and V. Some relevant synthetic strategies also are found in US Patent 5,334,761, which is incorporated by reference. A primary alcohol moiety is linked to the quaternary nitrogen and then oxidized to the corresponding carboxylic acid. The carboxylate is then coupled with a variety of alcohols, thiols, and amines to generate the corresponding esters, thioesters, and amides respectively. (See page 53.)

See also Scheme III on page 73; Example 1 on page 59 for the preparation of DMRIE carboxylate; and Example 1B on page 59 for the preparation of DORIE carboxylate. Thus, these two compounds are described in the Specification.

Once the carboxylates were prepared, the amides listed in Claim 86 were synthesized. As stated on page 53, lines 20-22 of the Specification: "For example, the preparation of DMRIE carboxylate propyl amide was effected by DCC-catalyzed coupling of propyl amine with DMRIE carboxylate." See also Example 3 on pages 59-60 for the synthesis of DMRIE carboxylate propyl amide. Example 3A on page 60 provides the preparation of DMRIE carboxylate methionine-methylester amide, Example 3B provides DMRIE carboxylate methionine-leucine-methylester amide, and Example 3C provides DMRIE carboxylate methionine-leucine-phenyl-alanine-methylester amide.

Therefore, it is clearly established in the Specification that Applicant described the compounds listed in Claim 86 and was in possession of them as indicated by their syntheses.

Finally, Applicant refers the Examiner to US Patent 6,670,332, which is the parent to the present application. A review of issued Claim 11, for example, shows the same list of

compounds as that in pending Claim 86. For all of these reasons, Applicant asserts that Claim 86 does comply with the written description requirement and the rejection should be withdrawn.

Rejections under 35 USC §112, second paragraph

1) Claims 68 and 85 have been rejected as allegedly indefinite due to the definition of “Z” and its alleged overlap with the definition of “R<sub>6</sub>”, when R<sub>6</sub> is an amino acid, peptide, etc. The Office Action states on page 8: “...(1) R<sub>6</sub> is defined as being an amino acid, peptide, ..., not Z, and (2) the narrower limitation of Z being selected from the group consisting of O, S, NR<sub>1</sub>, NH and Se conflicts with the broader limitation of Z being apparently any atom of an amino acid, peptide, ....” [Emphasis added.] Applicant respectfully traverses.

The language at issue from Claim 68 reads:

“



wherein Z is selected from the group consisting of O, S, NR<sub>1</sub>, NH, and Se;

R<sub>6</sub> is selected from the group consisting of H, R<sub>3</sub>, and R<sub>4</sub>, and,

when Z is O, NH, NR<sub>1</sub>, or S, R<sub>6</sub> can further be an amino acid, peptide, polypeptide, protein, mono-, di- or polysaccharide,

wherein Z is an atom of said amino acid, peptide, polypeptide, protein, mono-, di- or polysaccharide; ...”

Please note that when Z is Se, R<sub>6</sub> cannot be an amino acid, peptide, etc. Therefore, R<sub>6</sub> can only be an amino acid, peptide, etc. when Z is O, NH, NR<sub>1</sub>, or S. Looking at the structure presented above, Z is placed between the carbonyl and the R<sub>6</sub>. Thus, the carbonyl and Z are a

linker, or are part of the overall amino acid, peptide, etc. of  $R_6$  and are located at the ‘beginning’ or ‘ending’ of the amino acid, peptide, etc. Given the placement of Z and its definition of being only O, NH,  $NR_1$ , or S when  $R_6$  is an amino acid, peptide, etc., Applicant asserts that Z cannot be just any atom of the amino acid, peptide, etc.

The same arguments apply to rejected Claim 85, wherein Z is only  $NR_1$  or NH.

Applicant also respectfully points out that this same language is utilized in Claim 1 of US Patent 6,670,332, which is the parent to the instant application. Claim 2 of the ‘332 patent supports this understanding of the language, because Claim 2 reads: “... Z is O and  $R_6$  is an amino acid or peptide linked to Z as an ester.” Applicant requests that the rejection be withdrawn.

However, Applicant is willing to consider alternative language if the Examiner has a particular suggestion. In addition, Applicant’s undersigned representative is available to discuss alternative language, if the Examiner would prefer to do so.

2) Claims 71, 73-74, and 87 have been rejected due to the definition of “ $R_7$ ” and “ $R_8$ ”. (Claims 73-74 and 87 are dependent upon Claim 71, which contains the terms “ $R_7$ ” and “ $R_8$ ”). The allegedly confusing language reads:

“



$R_7$  and  $R_8$  are independently selected from the group defined for  $R_3$  and  $R_4$  and

one of R<sub>7</sub> and R<sub>8</sub> can further be an amino acid, peptide, polypeptide, protein, mono-, di- or polysaccharide, wherein an amino nitrogen of said amino acid, peptide, polypeptide, protein, mono-, di- or polysaccharide is the N to which R<sub>7</sub> or R<sub>8</sub> is attached;"

Applicant respectfully traverses. When R<sub>7</sub> and R<sub>8</sub> are the same substituents as those defined for R<sub>3</sub> and R<sub>4</sub>, then R<sub>7</sub> and R<sub>8</sub> can both be the same or different substituents just like R<sub>3</sub> and R<sub>4</sub>.

In addition, only one of R<sub>7</sub> and R<sub>8</sub> also can be an amino acid, peptide, etc. and the nitrogen of the above structure is part of that amino acid, peptide, etc. For example, if R<sub>8</sub> is an amino acid, then R<sub>7</sub> can only be selected from the group defined for R<sub>3</sub> and R<sub>4</sub>. And R<sub>7</sub> will attach to the nitrogen in the structure, but the nitrogen will be part of the amino acid of R<sub>8</sub>.

Again, Applicant respectfully notes that this same language is found in US Patent 6,670,332 at Claim 12. For these reasons, the challenged language in Claim 71 is clear and not indefinite. As a result, Applicant requests withdrawal of the rejection.

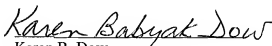
In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111  
U.S. Application No.: 10/748,853

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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